UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

AMAG PHARMACEUTICALS, *Plaintiff,* v. SANDOZ, INC., *Defendant.*	Civil Action No.: 16-cv-1508 (PGS) **MEMORANDUM AND ORDER**

This matter is before the Court on Defendant Sandoz, Inc.'s (hereinafter "Sandoz") motions in limine. There are two in limine motions before the Court.[1] They are: (1) to preclude introduction of evidence comparing Sandoz's product to the alleged commercial embodiment (ECF No. 101); and (2) to preclude Plaintiff from asserting that a nexus exists regarding the patent-in-suit. (ECF No. 102).

"[A] motion in limine is designed to narrow the evidentiary issues for trial and to eliminate unnecessary trial interruptions. *Bradley v. Pittsburgh Bd. of Educ.*, 913 F.2d 1064, 1069 (3d Cir. 1990). "An in limine motion is not a proper vehicle for a party to ask the Court to weigh the sufficiency of the evidence to support a particular claim or defense, because "[t]hat is the function of a motion for summary judgment, with its accompanying and crucial procedural safeguards."

On the first motion to preclude introduction of evidence comparing Sandoz's product to a commercial embodiment, Defendant has not pointed to any specific paragraphs or the testimony

[1] One motion (to Preclude Plaintiff from Offering Cumulative or Duplicative Expert Testimony (ECF Nos 99 and 100) was withdrawn as Defendant reached an agreement with Plaintiff regarding Plaintiff's expert, Dr. Vincent M. Rotello, and regarding parties' effort to limit duplicative or cumulative testimony at trial. Parties have also agreed to reserve their respective rights in the Pre-Trial Order to raise objections regarding the same issue as necessary. (See ECF No. 109).

of any particular witness which specifically concerns the bioequivalence of the products. As such, this motion looks more like a summary judgment motion than one attempting to limit evidence. On the other hand, Plaintiffs contends that it will present limitation-by-limitation evidence to establish Defendant's proposed generic product will infringe the asserted claims; but some bioequivalence evidence may be educed during testimony.

As a general rule, "it is error for a court to compare in its infringement analysis the accused product or process with the patentee's commercial embodiment or other version of the product or process; the only proper comparison is with the claims of the patent." *Zenith Labs., Inc. v. Bristol-Myers Squibb Co.*, 19 F.3d 1418, 1423 (Fed. Cir. 1994). Nevertheless, "[o]ur case law does not contain a blanket prohibition against comparing the accused product to a commercial embodiment." *Adams Respiratory Therapeutics, Inc. v. Perrigo Co.*, 616 F.3d 1283, 1288 (Fed. Cir. 2010). Compliant with an exception to the general rule, the Court will accept a comparison of an accused product to a commercial embodiment "where the commercial embodiment met all of the claim limitations." *Id.* at 1289. As such, the motion is denied.

The second motion is to preclude Plaintiff from asserting secondary considerations because there is no nexus between the purported inventive features and the secondary considerations. As with the first motion, it is very broad and looks more like summary judgment than a motion in limine.

Defendant's argument appears to be tri-fold: (1) Plaintiff has failed to provide evidence required to prove there is a nexus warranting introduction of secondary consideration; (2) Plaintiff failed to provide evidence supporting that the novel element of the asserted claims, namely autoclavability, rather than attributes that were prior art, warrant the introduction of secondary consideration; (3) Plaintiff has failed to establish a causal nexus between the asserted claims and

Plaintiff's identified secondary considerations of non-obviousness and between Defendant's infringement of the patents-in-suit and the irreparable harm Plaintiff would suffer. Overall, the issues presented appear to point to Plaintiff's insufficiency of evidence and request broad exclusion of evidence that has not been itemized.

As a general rule, evidence of secondary consideration "is only significant if there is a nexus between the claimed invention and the [secondary consideration]" so that the non-obvious feature of the invention accounts for secondary consideration. *Ormo Corp. v. Align Tech., Inc.*, 463 F.3d 1299, 1311-12 (Fed. Cir. 2006). "When the patentee can demonstrate the secondary consideration, and the successful product is the invention disclosed and claimed in the patent, it is presumed that the secondary consideration is due to the patented invention." *Id.* Whereas, where the secondary consideration of a claimed invention is due to an unclaimed feature of the device, the secondary consideration is irrelevant. (i.e. if the feature leading to the secondary consideration was known in the prior art.) *Id.* at 1312.

While the ultimate question of patent validity is one of law, the issue of obviousness "lends itself to several basic factual inquiries." *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966). The inquiry takes account of review of "secondary considerations," which may include evidence of commercial success, long-felt but unsolved needs, failure of others, and unexpected results. *Id.* The weight to be given any objective evidence is made on a case-by-case basis. Id.

At oral argument, the Court inquired about the specific evidence that Defendant sought to exclude since the motion's request appeared to be broad. Defendant narrowed the issue seeking to prevent the entry of evidence not included in the reports and not discovered. In response, Plaintiff confirmed that it is not intending to go beyond the issues discussed in the expert report.

Again, in this motion, it is unclear exactly what evidence Defendant seeks to exclude; the request appears to seek a sweeping exclusion of all secondary considerations. Further, the question presented by the motion seem to raise the issue of sufficiency of evidence. Although Defendants presents legitimate issues, a motion in limine is not the appropriate stage for their resolution. "[A] motion in limine is designed to narrow the evidentiary issues for trial and to eliminate unnecessary trial interruptions. *Bradley v. Pittsburgh Bd. of Educ.*, 913 F.2d 1064, 1069 (3d Cir. 1990). "An in limine motion is not a proper vehicle for a party to ask the Court to weigh the sufficiency of the evidence to support a particular claim or defense, because "[t]hat is the function of a motion for summary judgment, with its accompanying and crucial procedural safeguards." *Bowers v. NCAA*, 563 F. Supp. 2d 508, 532 (D.N.J. 2008).

A complete exclusion of all secondary consideration evidence at this stage is premature. *Uniloc USA, Inc. v. Microsoft Corp.*, 632 F. Supp. 2d 147, 158 (D.R.I. 2009). Accordingly, the Court finds Defendant's request to be broad and outside the scope of a motion in limine. The Court further finds that the issues presented by Defendant will be best reserved for determination at trial. As such, this motion is denied.

ORDER

This matter having come before the Court on Defendant Sandoz, Inc.'s (hereinafter "Sandoz") motions in limine; and for the reasons set forth above; and for good cause having been shown;

IT IS on this 22nd day of February, 2018;

ORDERED that the motion to preclude introduction of evidence comparing Sandoz's product to the alleged commercial embodiment (ECF No. 101) is denied; and it is further

ORDERED that the motion to preclude Plaintiff from asserting that a nexus exists regarding the patent-in-suit (ECF No. 102) is denied.

PETER G. SHERIDAN, U.S.D.J.